UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,633	10/14/2003	Michael S. Kopreski	00-1312-L	5239

7590 06/21/2007

McDonnell Boehnen Hulbert & Berghoff
32nd Floor
300 S. Wacker Drive
Chicago, IL 60606

EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
06/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/684,633	KOPRESKI, MICHAEL S.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2007*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-28* is/are pending in the application.

4a) Of the above claim(s) *5-10 and 17-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on March 15, 2007 has been entered. The claims pending in this application are claims 1-3 and 5-28 wherein claims 5-10 and 17-28 have been withdrawn due to restriction requirement and species election. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response filed on March 15, 2007. Therefore, claims 1-3 and 11-16 will be examined.

Election/Restrictions

2. This application contains claims 23-28 drawn to an invention nonelected in the reply filed on September 28, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

3. Claim 2 is objected to because of the following informality: "the non-cellular fraction blood" should be "the non-cellular fraction of blood".

4. Claims 12 and 15 are objected to because of the following informality: "A method" in line 1 should be "The method".

Appropriate correction is required.

Response to Arguments

In page 8, third paragraph of applicant's remarks, applicant argues that the amendments in claims 12 and 15 have overcome the objection.

This argument has been fully considered but it is not persuasive toward the withdrawal of the objection because applicant has not changed "A method" in line 1 of the claims to "The method".

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Scope of Enablement

Claims 1-3 and 11-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting her-2/neu RNA in plasma or serum in certain human cancer patients, does not reasonably provide enablement for (1) using the methods recited in claims 1 and 2 for detecting, diagnosing, evaluating or monitoring a caner or premaligant disease wherein said cancer or premalignant disease comprises neoplastic cells that express or over-express one or more species of RNA that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B 1 RNA by amplifying a RNA species that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B 1 RNA, or any combination thereof in a non-cellular fraction of blood from a human; (2) using the method recited in claim 3 for extracting an RNA species from a non-cellular fraction of blood from any kind of species using a probe that hybridizes with said RNA species wherein the RNA species is epidermal growth factor RNA, her-2/neu RNA or

nuclear ribonucleoprotein A2/B 1 RNA; (3) using the methods recited in claims 11-13 for selecting a human or animal having a cancer that over-expresses her-2/neu for a her-2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of blood from the human or animal for her-2/neu RNA or cDNA; and (4) using the methods recited in claims 14-16 for monitoring response in a human or animal to a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of blood from the human or animal for her-2/neu RNA or cDNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance in the specification to show that: (1) the methods recited in claims 1 and 2 can be used for detecting, diagnosing, evaluating or monitoring a caner or premaligant disease wherein said cancer or premalignant disease comprises neoplastic cells that express or over-express one or more species of RNA that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc

RNA, or heterogeneous nuclear ribonucleoprotein A2/B 1 RNA by amplifying a RNA species that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B 1 RNA, or any combination thereof in a non-cellular fraction of blood from a human; (2) the method recited in claim 3 can be used for extracting an RNA species from a non-cellular fraction of blood from any kind of species using a probe that hybridizes with said RNA species wherein the RNA species is epidermal growth factor RNA, her-2/neu RNA or nuclear ribonucleoprotein A2/B 1 RNA; (3) the methods recited in claims 11-13 can be used for selecting a human or animal having a cancer that over-expresses her-2/neu for a her-2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of blood from the human or animal for her-2/neu RNA or cDNA; and (4) the methods recited in claims 14-16 can be used for monitoring response in a human or animal to a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of blood from the human or animal for her-2/neu RNA or cDNA. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether: (1) the methods recited in claims 1 and 2 can be used for detecting, diagnosing, evaluating or monitoring a caner or premaligant disease wherein said cancer or premalignant disease comprises neoplastic cells that express or over-express one or more species of RNA that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B 1 RNA by amplifying a RNA species that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B 1 RNA, or any combination thereof in a non-cellular fraction of blood from a human; (2) the method recited in claim 3 can be used for

extracting an RNA species from a non-cellular fraction of blood from any kind of species using a probe that hybridizes with said RNA species wherein the RNA species is epidermal growth factor RNA, her-2/neu RNA or nuclear ribonucleoprotein A2/B 1 RNA; (3) the methods recited in claims 11-13 can be used for selecting a human or animal having a cancer that over-expresses her-2/neu for a her-2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of blood from the human or animal for her-2/neu RNA or cDNA; and (4) the methods recited in claims 14-16 can be used for monitoring response in a human or animal to a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of blood from the human or animal for her-2/neu RNA or cDNA.

Claims 1 and 2 are directed to a method for detecting, diagnosing, evaluating or monitoring cancer or premalignant disease in human wherein said cancer or premalignant disease comprises neoplastic cells that express or over-express one or more species of RNA that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B 1 RNA by amplifying a RNA species that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B1 RNA, or any combination thereof in a non-cellular fraction of blood from a human. First, since it is known that heterogeneous nuclear ribonucleoprotein A2/B 1 is overexpressed in normal and abnormal bronchial epithelium of chronic smokers (see abstract from Clinical Cancer Research, 4, 1631-1640, 1998) and breast cancer cells from breast cancer patients (see abstract from Breast Cancer Research and Treatment, 66, 217-224, 2001), and claims 1 and 2 do not require a control and do not require that the human is not a chronic smoker and the cancer is a specific cancer, when the human is a

chronic smoker with breast cancer, it is unclear that heterogeneous nuclear ribonucleoprotein A2/B1 RNA from a non-cellular fraction of blood of the human is from bronchial epithelium cells or is from breast cancer cells. Second, since the specification does not provide guidance to show that two or more of epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, and heterogeneous nuclear ribonucleoprotein A2/B1 RNA can be detected in the same non-cellular fraction of blood from a human having a cancer or premalignant disease, it is unclear how to amplify any combination of epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, and heterogeneous nuclear ribonucleoprotein A2/B 1 RNA.

Claim 3 is directed to a method for extracting an RNA species from a non-cellular fraction of blood from any kind of species using a probe that hybridizes with said RNA species, wherein the RNA species is epidermal growth factor RNA, her-2/neu RNA, or heterogeneous nuclear ribonucleoprotein A2/B 1 RNA. Since the specification does not provide guidance to show that epidermal growth factor RNA, her-2/neu RNA, or heterogeneous nuclear ribonucleoprotein A2/B 1 RNA can be detected in a non-cellular fraction of blood from any kind of species, it is unclear how to extract an RNA species from a non-cellular fraction of blood from any kind of species using a probe that hybridizes with said RNA species wherein the RNA species is epidermal growth factor RNA, her-2/neu RNA, or heterogeneous nuclear ribonucleoprotein A2/B 1 RNA. Furthermore, since it is known that some of cancers such as Hodgkin and Hon-Hodgkin lymphoma do not have overexpression or even any expression of her-2/neu RNA (see abstract in page 574 of Arch. Pathol. Lab. Med., 126, 574-576, 2002), it is unclear how to extract an RNA species from blood plasma or serum from a patient having

Hodgkin and Hon-Hodgkin lymphoma using a probe that hybridizes with said RNA species wherein the RNA species is her-2/neu RNA.

Claims 11-13 are directed to selecting a human or animal having a cancer that overexpresses her-2/neu for a her2/neu-directed therapy. Since the claims do not require a control and does not set up a selection standard, and it is known that human normal cell also contains her-2/neu (see abstract in Oncogene, 5, 953-962, 1990), it is unclear how to differentiate a human or animal having a cancer that overexpresses her-2/neu from a human without a cancer and how to select a human or animal having a cancer that overexpresses her-2/neu for a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of blood of the human or animal for her-2/neu RNA or cDNA. Furthermore, the specification does not provide guidance to show to select any kind of animal for a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of blood of any kind of animal for her2/neu RNA or cDNA.

Claims 14-16 are directed to a method for monitoring response in a human or animal to a her2/neu-directed therapy. Since it is known that some of cancers such as Hodgkin and Hon-Hodgkin lymphoma do not have overexpression or even any expression of her-2/neu RNA (see abstract in page 574 of Arch. Pathol. Lab. Med., 126, 574-576, 2002) and the claims do not limit that the human is a human having a specific cancer, it is unclear how to select a human with Hodgkin and Hon-Hodgkin lymphoma for monitoring response for a her2/neu-directed therapy. Furthermore, since the claims do not require a control and do not set up a selection standard, and it is known that both human cancer cells (see the specification, page 25, Example 1) and human normal cells contain her-2/neu (see abstract in Oncogene, 5, 953-962, 1990), it is unclear that

her2/neu RNA from a non-cellular fraction of blood of the human or animal is from human cancer cells or human normal cells and how to select a human or animal for monitoring response for a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of blood of the human or animal for her-2/neu RNA or cDNA. In addition, the specification does not provide guidance to show to select any kind of animal for a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of blood of any kind of animal for her2/neu RNA or cDNA.

With above unpredictable factor, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. The undue experimentation at least includes to test whether: (1) the methods recited in claims 1 and 2 can be used for detecting, diagnosing, evaluating or monitoring a caner or premaligant disease wherein said cancer or premalignant disease comprises neoplastic cells that express or over-express one or more species of RNA that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B 1 RNA by amplifying a RNA species that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B 1 RNA, or any combination thereof in a non-cellular fraction of blood from a human; (2) the methods recited in claim 3 can be used for extracting an RNA species from a non-cellular fraction of blood from any kind of species using a probe that hybridizes with said RNA species wherein the RNA species is epidermal growth factor RNA, her-2/neu RNA or nuclear ribonucleoprotein A2/B 1 RNA; (3) the methods recited in claims 11-13 can be used for selecting a human or animal having a cancer that over-expresses

her-2/neu for a her-2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of blood from the human or animal for her-2/neu RNA or cDNA; and (4) the methods recited in claims 14-16 can be used for monitoring response in a human or animal to a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of blood from the human or animal for her-2/neu RNA or cDNA.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 2, and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 is rejected as vague and indefinite. Since premalignant disease is not a cancer, it is unclear that premalignant disease comprises neoplastic cells as recited in preamble of the claim. Please clarify.

10. Claim 11 is rejected as vague and indefinite because the phrase "A method for selecting for a her2/neu-directed therapy a human or animal having cancer that over-expresses her-2/neu" does not make sense. Please clarify.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Balazs *et al.*, (WO 90/09456, published on August 23, 1990).

Regarding claims 1 and 2, Balazs *et al.*, teach a method for detecting, diagnosing, evaluating or monitoring cancer or premalignant disease in a human wherein said cancer or premalignant disease comprises neoplastic cells that express or over-express one or more species of RNA that is epidermal growth factor receptor RNA or c-myc RNA, the method comprising the steps of: a) extracting total extracellular RNA from a non-cellular fraction of blood from a human, wherein a fraction of said extracted RNA comprises one or more RNA species that is epidermal growth factor receptor RNA (ie., Erb^B RNA) or c-myc RNA, or any combination thereof; b) amplifying or signal amplifying said fraction of the extracted RNA or cDNA prepared therefrom, either qualitatively or quantitatively, using primers or probes specific for said RNA species to produce an amplified product or using labeled primers or probes specific for said RNA species to produce an amplified signal; and c) detecting either quantitatively or qualitatively the amplified product or amplified signal wherein cancer or premalignant disease comprising neoplastic cells that express or over-express one or more RNA species that is epidermal growth factor receptor RNA or c-myc RNA is detected, diagnosed, evaluated or monitored as recited in claim 1 wherein the non-cellular fraction of blood is blood plasma or serum as recited in claim 2 (see pages 14-19).

Therefore, Balazs *et al.*, teach all limitations recited in claims 1and 2.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs *et al.,* as applied to claims 1 and 2 above, and further in view of Revillion *et al.,* (Clinical Chemistry, 43, 2114-2120, 1997).

Regarding claim 3, Balazs *et al.,* teach a method for extracting an RNA species (ie., the PCR product) from a non-cellular fraction of blood (ie., blood plasma) using a probe (ie., the primers) that hybridizes with said RNA species, wherein the RNA species is epidermal growth factor receptor RNA (ie., Erbb) as recited in claim 3 (see pages 14-19).

Balazs *et al.,* do not disclose that said RNA species is her-2/neu-2 RNA as recited in claim 3. Note that her-2/neu-2 is one of epidermal growth factor receptors.

Revillion *et al.,* teach to RT-PCR her-2/neu-2 (erbB-2) gene in the presence of her-2/neu-2 primers (see pages 2115 and 2116).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have extracted an RNA species (ie., the PCR product) from a non-cellular fraction of blood (ie., blood plasma) using a probe (ie., the primers of her-2/neu-2) that hybridizes with said RNA species, wherein the RNA species is her-2/neu-2 (erbB-2) RNA in view of references of Balazs *et al.,* and Revillion *et al.*. One having ordinary skill in

the art has been motivated to do so because Revillion *et al.*, have successfully amplified her-2/neu-2 (erbB-2) gene in the presence of her-2/neu-2 primers by RT-PCR (see pages 2115 and 2116). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to amplify one of epidermal growth factor receptor RNAs such as her-2/neu-2 (erbB-2) RNA from a non-cellular fraction of blood (ie., blood plasma) in view of references of Balazs *et al.*, and Revillion *et al.*, so that an RNA species (ie., the PCR product) from a non-cellular fraction of blood (ie., blood plasma) using a probe (ie., the primers of her-2/neu-2) that hybridizes with said RNA species wherein the RNA species is her-2/neu-2 (erbB-2) RNA as recited in claim 3.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. No claim is allowed.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

June 7, 2007

FRANK LU
PRIMARY EXAMINER